

*Application No .10/814,244*  
*Reply to Office Action dated January 2, 2008*

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## REMARKS

Claims 1 to 32 were examined. Claims 1, 15, 21, and 31 were amended. Claims 2-14, 16-20, 22-30 and 32 remain unchanged. Claims 33-39 were added. Claims 1-39 now stand in the application.

Claims 1 and 21 have been amended by adding the term "wherein the method does not include any evaporation and reconstitution steps".

Claim 15 has been amended by deleting the trademark symbols.

Claim 31 has been amended by adding the method steps of claim 1. Support for the steps can be found in paragraph [0070].

Claims 33-39 have been added. Claims 33-37 are directed to methods for the analysis of "free" antiretroviral drugs. The claims include a method step of purifying the sample, for example, by equilibrium dialysis or by use of molecular cutoff filters. Examples of molecular cutoff filters are provided in claim 37. Support is found in paragraph [0070]. Claim 38 is directed to the analysis of tenofovir. Support is found in paragraphs [0056] to [0060]. Claim 39 is dependent on claim 1. Support is found in Example 2, paragraphs [0056] to [0060].

### **Claim rejections 35 USC § 112**

#### Claim 15

The Examiner has rejected claim 15 for being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner states that it is unclear what elements constitute any of the three trademarked spectrometers. The Examiner further states that it is unclear if the claim would cover someone that has modified their spectrometer.

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Applicant has removed the trademark signs from claim 15.

#### Claims 31-32

The Examiner states that claims 31-32 are directed to the use of a mass spectrometer to analyze a sample, but it is unclear what method/process applicant is intending to encompass.

Applicant has amended claims 31-32 by adding method steps as follows:

- (a) providing a sample comprising at least two antiretroviral drugs from at least two classes of antiretroviral drugs;
- (b) introducing the sample comprising at least two antiretroviral drugs from at least two classes of antiretroviral drugs into a mass spectrometer; and
- (c) analyzing the sample using the mass spectrometer.

#### **Claim rejections under 35 U.S.C. 101**

#### Claims 31-32

The Examiner states that the claimed recitation of a use without setting forth method steps results in an improper definition of a process.

Applicant has amended claims 31-32 by adding method steps as described above.

#### **Claim rejections 35 USC § 102(b)**

#### Volosov et al.

The Examiner objected to claims 1-32 citing Volosov et al. The Examiner states that Volosov et al. discloses a simple method for the analysis of antiretrovirals by liquid chromatography tandem mass spectrometry.

Applicant submits that Volosov et al. is the Applicant's own work and submits a declaration under 37 CFR 1.132. Volosov et al. was published electronically on April 23, 2002 and in a journal on April 30, 2002. Applicant submits an email from the

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publisher and information from the publisher's website indicating the publication dates. The claim date of the present application is April 14, 2003, which falls in the one year grace period. Accordingly, Volosov et al. is not a proper citation under 35USC § 102(b). Applicant requests that the objection be withdrawn.

Shoup et al.

The Examiner objected to claims 1-2, 4-8, 10, 19, 21-22, 24-26 and 31-32 citing Shoup et al. The Examiner states that Shoup et al. discloses a robotic solid phase extraction at neutral pH with analysis using tandem mass spectrometer.

Applicant submits that the method of Shoup et al. differs from that of the present invention in that Shoup et al. uses a complicated extraction procedure in contrast to the simple steps outlined in the present claims, that includes evaporation and reconstitution of the analyte. The claims have been amended by specifying that the method of the analysis of the antiretrovirals does not include any evaporation or reconstitution of the analyte. Applicant submits that the objection has been overcome.

Information Disclosure Statement:

The Examiner states that the Information Disclosure Statement filed August 15, 2007 fails to comply with 37 CFR 1.98(a)(1), which requires (1) list of all patents, publications, applications (2) US patents and applications listed in a separate section, (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list and (4) column that provides blank space for the Examiner's initials, and (5) a heading that indicates that the list is an information disclosure statement.

The Examiner states that the information disclosure statement has been placed in the file, the information referred to therein has not been considered unless the reference is listed on a PTO-892 Form. Applicant provides form PTO-892 with the references listed thereon.

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Applicant believes that all of the issues addressed in the outstanding Action have been addressed in this response, and thus request allowance of the application.

In the event that any issues remain, the Examiner is invited to telephone the undersigned at (416) 865-8242 with any proposal to advance prosecution.

Yours very truly,

April 2, 2008  
Date



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*Enclosures:*

- (1) Declaration from Steven J. Soldin and Exhibit A containing copy of Volosov et al.*
- (2) A copy of an email from the publisher of Volosov et al.*